Exhibit A

Health Hazard Evaluation

DATE: December 17, 2004

TO: Doug Uelmen, BPV QA

FROM: David Ciavarella, M.D.

RE: Recovery® Filter – Consultant's report

Summary: Seventy-six reports of potentially serious hazards have been reported; 32 of these were judged to be serious, and 10 reports were associated with patient death. Total Recovery filter sales during this reporting period (through December 13, 2004) are 20,827 units. Reporting rates of death and other potentially serious complications for the Recovery filter remain below those reported in the literature. However, literature data are not directly comparable to these reporting rates. An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters. However, these databases are subject to known, significant biases that make calculation or comparison of incidence rates among products unreliable and inadvisable (according to experts and the FDA). Nevertheless, the number of reported complaints, and the size of the differences between Recovery and other filters, warrant further investigation.
Conclusion: The Frequency category for serious injury (Critical Severity rating) is Occasional (32/20,827, or 0.153%). The Frequency category for non-serious injury (Marginal Severity rating) is Occasional (44/20,827, or 0.21%).

Description of the Problem: Based on awareness of reports of patient death associated with migration of the Recovery inferior vena cava (IVC) filter, Bard requested an independent study of the risks and benefits of the Recovery filter, with an emphasis on its use in bariatric surgery and trauma patients. A consultant was retained for this purpose. The consultant's assignment had three components: 1) Perform a literature review of the risks and benefits of IVC filters, with an emphasis on bariatric surgery and trauma patients; 2) Review internal complaint files for the Recovery filter, and compare its reported adverse events rates to those of competitors' IVC filter by use of the MAUDE and IMS (sales) databases or other means; & 3) develop options for clinical studies that might provide information required to assess the risks and benefits of use of the Recovery filter.

The consultant made the following points:

1) The existing literature is of poor quality, with insufficient randomized, controlled trials (RCT) to definitively establish the effectiveness of IVC filters. However, widespread consensus exists in the medical community, obtained via clinical studies of lower credibility than the RCT (such as case reports, case series and prospective non-randomized studies of small size) and expert opinion, that IVC filters lower the likelihood of death from pulmonary embolus in patient groups thought to be at highest risk of this manifestation of venous thromboembolic disease. These high risk groups include patients who have already had a pulmonary embolus or in whom standard anticoagulation therapy cannot be given. However, the existing literature contains comparatively little information on a new generation of IVC filters, especially those with a removability feature (Recovery, Cook Tulip™ and Cordis OptEase™).

   Proper product comparisons can be only be drawn from clinical studies where patient populations are carefully defined, comparisons are made under controlled circumstances from equivalent pa-

tient groups, and adverse events are prospectively defined and sought for in an effective manner. Such studies do not exist for the Recovery filter or its competitors. Therefore, the consultant judged that the literature is an inadequate source of reliable information upon which to make a risk/benefit assessment for the Recovery filter, either alone or in comparison to other IVC filters.

2) The consultant's analysis of the reports to Bard of adverse events associated with Recovery, along with competitors' information available via the MAUDE and IMS databases, showed the following:
   a. Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters. The TrapEase filter was found to have a statistically significant increased reporting rate for IVC thrombosis when compared to reporting rates for other filters.

   b. These reported adverse event rates were analyzed in conjunction with a bench test performed at BPV. This test measured "migration resistance" in a simulated IVC. Recovery filter had the lowest mean migration resistance (50 mm Hg), just below that of the removable Tulip filter (55 mm Hg). Linear regression analysis showed a significant inverse correlation (R^2 values of 0.40 to 0.65) of reported migration rates to the migration resistance values in the bench test.

   c. An analysis of the quality and validity of this analytical approach (use of MAUDE and IMS databases to generate comparative event rates), however, was performed as well. Many references were found that discussed the inadvisability of using MAUDE data for this purpose. Reported event data are seriously flawed, due to underreporting, various acknowledged forms of bias (such as the known propensity for more reports of adverse events in newer products), and confounding effects (such as lack of comparability in patient groups). The FDA has stated that such an approach is "...problematic, if not completely biased" [1] and "Accumulated reports cannot be used to calculate incidence or to estimate drug risk. Comparisons between drugs cannot be made from these data.". [2] Similar biases were discussed for use of the IMS sales data, in particular, the known lag period that exists between data collection and data publication, leading to large biases in data for products that are new or where indications are in evolution. Thus, actual incidence rates cannot be determined by this approach; these data are better interpreted as providing a signal for further investigation.

   d. A risk/benefit assessment has not been done, because the potential unique benefits of the Recovery filter (e.g., in certain patient groups) have not been evaluated as part of the consultant's report.

3) Little formal analysis has been completed with respect to potential clinical trials to obtain more definitive risk/benefit information. A randomized, controlled trial is the gold standard for determining risks and benefits; however, such a study is likely to require many subjects and therefore be difficult or impossible to execute. The consultant stated that a survey of physicians regarding their use of IVC filters and/or an analysis of data from a large payor or provider organization might be alternative approaches that might provide useful information in a shorter timeframe.

In addition to the consultant's report, a case-by-case analysis of all reported Recovery complaints as of December 13, 2004 related to filter migration, filter fracture, IVC thrombosis, IVC perforation and recurrent pulmonary embolus was performed.

The Actual Occurrence of Injuries: Serious injury is defined here as reported death, or necessity for a surgical intervention to prevent death or serious injury. Reported recurrent pulmonary embolus or IVC thrombosis despite the presence of the filter were also classified as serious injury. In addition, migration of a filter or filter fragments to the heart or lung, or the presence of a filter fragment outside the vasculature, were classified as serious injury, since there is a possibility that serious injury could develop in the future.

With these criteria, there were a total of 32 reported serious injuries, a reporting rate of 0.153%. Details of these reports are given below.

Human Exposure to the Problem: About 20,827 Recovery filters have been distributed as of December 13, 2004.

General Consequences: The consequences of reported adverse events associated with the Recovery IVC filter depend upon the kind of event. Filter migration to the heart, especially when the filter is encased in thrombus, has been associated with sudden death. In some cases, filter migration is associated with trapping of clot before it reaches the heart, and it continues to perform its primary function despite the migration. Filter fracture may be asymptomatic, but has been associated with fragment embolization to the heart causing syncope and/or arrhythmias. IVC perforation is also generally asymptomatic, but it can lead to serious bleeding and, if occurring in conjunction with filter limb fracture, may be associated with fragment migration outside the IVC to nearby organs.

Population Exposed to the Risk: All patients in whom a Recovery filter is placed are potentially at risk for filter-associated adverse events.

Mitigating/Predisposing Factors in the Population at Risk: Unknown.

Nature & Seriousness of the Risk: The nature of the injury is generally related to the cardiovascular system, such as pulmonary embolus, myocardial or pericardial puncture or damage, or bleeding. There was one case of renal vein thrombosis requiring dialysis, listed as a serious event because the filter migrated above the renal veins, thus potentially allowing clot in the lower IVC to propagate to the renal veins. However, it is also possible that renal vein thrombosis developed because of the underlying disease and was unrelated to the filter migration. There was one case of reported IVC thrombosis in a patient in whom recurrent pulmonary embolus was also reported. No further information about this case is available at this time.

The seriousness of the risk ranged from reports of patient death to no effects. There were 10 reports of death. One death was reported in association with recurrent PE, while the other 9 were associated with filter migration. Six (6) of these migration-associated deaths were migrations to the heart of a thrombus-encased filter. In a seventh case, only a small amount of clot was attached to the filter, but large clots were present in the pulmonary arteries. In one case, it was not known whether the filter contained clot, and in the remaining 2 cases, physicians judged the deaths to be unrelated to the filter. In the first of these 2 cases, the filter, without adherent clot, flowed out of the ventricle at autopsy. A chest X-ray taken during CPR and just prior to death did not reveal the filter in the heart, and migration to the heart may have occurred due to CPR or post mortem. In the second case, a CT scan performed minutes prior to death revealed migration to the upper IVC. In this case, an autopsy was not performed, and the physician stated that death was not related to the filter.

Likelihood of Occurrence of the Problem: The number, severity classification and type of complication (hazard) reported for the Recovery filter are summarized in Table I.

Table I. Reporting Rates for Adverse Events Associated with the Recovery Filter

Hazard type	Total	Reporting Rate	Serious Injury(as above)	Reporting Rate
Death	10(8*)	0.048%(0.038%*)	10(8*)	0.048% (0.038%*)
Migration	25	0.12%	16 (14*)	0.077% (0.067%*)
Fractures	33	0.158%	12	0.058%
Perforation	15	0.072%	1	0.005%
P. embolus	3	0.014%	3	0.014%
[IVC Thrombosis	1**	0.005%	1	0.005%]
Total	76**	0.365%	32 (30)	0.153% (0.149%)

* Number and rates if the 2 migration-associated deaths that were judged not related to the filter are excluded.
** Recurrent pulmonary embolism was also reported in this case; therefore, the total number of patients/reports is listed as 76 and not 77.

A summary of reported rates for these filter-related complications in the literature is provided in Table II.[3] These rates refer to the use of permanent, non-removable filters.

Table II. Reported Rates of IVC Filter Complications Provided by Literature Review.
Threshold levels are quality improvement guidelines published by the Society of Interventional Radiologists. Reference: Grassi CJ, Swan TL, Cardella JF et al: Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003;14:S271-S275.

Hazard type	Reported rates		Threshold (for review)
Death	0.12%		< 1%
Filter Embolization*	2-5%	2%	
Fractures	2-10%		Not listed
Perforation	0-41%		Not listed
P. embolus	0.5-0.6%		5%
IVC Occlusion**	2-30		10%

* This is equivalent to Migration in the Table above listing Recovery reporting rates
** This is equivalent to IVC Thrombosis in the Table above

Likelihood of Harm if the Problem Occurs: See above for the reporting rates of serious injury, defined as described in **The Actual Occurrence of Injuries**.

Is the Product Essential to Health: Yes, in selected patient groups. As mentioned above, a general consensus exists for the utility of IVC filters in high risk patient groups despite the lack of definitive RCTs.

Is there an Alternative Available: Yes. Alternative permanent and removable IVC filters exist. However, the Recovery filter is unique in the length of the implant period. The Recovery implant period is not limited in the Recovery instructions for use (IFU), and can be utilized as a permanent filter. The clinical experience for the other removable filters, as discussed in the product IFUs, reports short implant periods (mean implant period about 2-3 weeks) before filter removal must be undertaken.

Must the Problem Device be Removed or Corrected Surgically: Yes, in some cases.

Is the Problem Expected & Within an Acceptable Statistical Range: From the analysis of the MAUDE and IMS databases, Recovery reporting rates are significantly higher than those of other filters. In conjunction with these data, there appears to be a significant correlation, although R^2 values are only in the 0.5 range, of the migration reporting rates with the simulated migration resistance bench test. However, the flaws in the data collection methodologies makes calculation and comparison of actual incidence rates impossible from these data, and no definitive conclusions as to relative performance can be made. Adverse events rates reported in the literature are well above these reporting rates. But, as discussed above, direct comparisons of reporting rates to literature-derived rates are not possible because mostly permanent filters have been studied and the data have been collected using markedly different detection methods and patient populations. However, further investigation of these reported adverse events is warranted because of the size of the differences in the reporting rates and the correlation with the bench test of migration resistance.

Can the Problem be Corrected in the Field: No.

Is the Problem or Health Hazard Obvious to the User: No.

Can the Product Continue to be Used with Proper Warnings: One could consider providing summary information concerning the analysis of reporting rates to physicians in the context of the limitations of the data. Further work into the collection of survey data from surgeons or payors might be explored.

Is the Device Used Only by Specially Trained Health Care Professionals: Yes.

References:

[1]. Goldman SA. Limitations and strengths of spontaneous reports data. Clin Ther 1998; 20 Suppl C: C40-44.

[2]. Jones JK. Spontaneous reports cannot serve as a basis for comparison of two drugs. Am J Cardiol 2003;92:1141-1142.

[3]. Grassi CJ, Swan TL, Cardella JF, et al: Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003;14:S271-S275.